Aventis Pharmaceuticals

August 1, 2002

Via fax and UPS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0231
Draft Guidance Q1F Stability Data Package for Registration in Climatic Zones III and IV [67FR 40951, June 14, 2002]

Dear Sir/Madam:

Aventis Pharmaceuticals Inc. would like to thank you for the opportunity to comment on the above-referenced draft guidance entitled "Q1F Stability Data Package for Registration in Climatic Zones III and IV".
This draft guidance, an annex to an ICH guidance entitled "Q1A(R) Stability testing of New Drug Substances and Products", defines an approach for broader use of Q1A(R) for territories in climatic zones III and IV.
The development of the draft guidance on stability data package for registration in climatic zones III and IV is welcomed. The underlying principles are generally sound and acceptable. We offer the following comments/clarification for your consideration.

1. INTRODUCTION

1.1 Objectives of the Guideline

Page 1 – literature references
(See Schumacher P., Aktuelle Fragen zur Haltbarkeit von Arzneimitteln [Current questions on drug stability] Pharmazeutische Zeitung, 1974, 119:321-324)

Literature references should not be included in the text of the guidance. A list of literature references should be given at the end of the document.

02D-0231 CS

1.2 Background

Page 1 – first paragraph, first sentence

The parent guideline defines the stability data package for the ICH tripartite regions (EC, Japan, and the United States).

The Federal Register notice clearly mentions that the ICH tripartite regions (the EU, Japan, and the United States) are in climatic zones I or II. This statement should be included in the proposed Q1F guidance to make clear that Q1F does not apply to the ICH tripartite regions. We propose to modify this sentence as follows: "*The parent guideline defines the stability data package for the ICH tripartite regions (EC, Japan, and the United States)* **which are in climatic zones I or II.**"

We believe that it will be very helpful to create an annex with a list of countries that are in climatic zones I, II, III and IV.

1.3 Scope of the Guideline

Page 1

This document is an annex to the parent guideline and recommends the long term storage condition to determine the data package considered sufficient for a registration application for drug substances and products intended to be marketed in Climatic Zones III and IV.

Since the proposed Q1F is an annex to the parent guideline "Q1A(R) Stability Testing of New Drug Substances and Products", it should be emphasized that Q1F primarily applies to new drug substances and products as the parent guideline. We propose rewording this paragraph as follows: "*This document is an annex to the parent guideline and recommends the long term storage condition to determine the data package considered sufficient for a registration application for* **New Drug Substances and associated Products** *intended to be marketed in Climatic Zones III and IV.*"

2. GUIDELINES

2.1 Continuity with the Parent Guideline

Page 1 – first paragraph – first sentence

This guideline should be read in conjunction with the parent guideline and subsequently published annexes (Q1B, Q1D, Q1E). The recommendations in the parent guideline and annexes should be followed unless specific alternatives are described within this annex.

We propose to also refer to Q1C guideline "Stability Testing for New Dosage Forms" to allow that reduced stability data (i.e. 6 months) can be accepted at the time of filing an application in the case for new formulations of already approved medicines. We propose rewording this sentence as follows "*This guideline should be read in conjunction with the parent guideline and subsequently published annexes (Q1B, Q1D,* **Q1C**, *Q1E).*"

Page 2 – last bullet: Semi-Permeable or impermeable containers

For stability testing of products in semi-permeable containers, the proposed Q1F guidance refers to the parent guideline Q1A(R) requesting for long-term study storage at 25°C ± 2°C/40% RH ± 5% and for accelerated study storage at 40°C ± 2°C/NMT 25% RH.

Climatic zone III is known to be warm and dry. In such climate, it is expected that the water loss will play a much more important role than in climatic zones I and II. Therefore, it could be not sufficient to apply the same long-term storage condition as the one required for climatic zones I and II (i.e. 25°C ± 2°C/40% RH ± 5%).

The WHO standard long-term storage condition for climatic zone III, 30°C ± 2°C/35% RH ± 5%, would be more appropriate.

For accelerated study, the storage condition required in the parent guideline for climatic zones I and II (i.e. 40°C ± 2°C/NMT 25% RH) is acceptable.

We believe that a specific paragraph addressing specific issues related to semi-permeable containers should be included in the proposed Q1F guidance.

2.2 Storage Conditions

Page 2 – second paragraph

For drug substances and products intended for registration applications within the ICH Tripartite regions, the parent guideline applies and long term testing will typically be conducted at 25°C ± 2°C/60% RH ± 5% RH. Where significant change occurs at any time during 6 months' storage at the accelerated condition, additional testing at the intermediate storage condition (30°C ± 2°C/65% RH ± 5% RH) should be conducted. Long term testing at 30°C ± 2°C/65% RH ± 5% RH can be a suitable alternative to 25°C ± 2°C/60% RH ± 5%. In this case, for an application in the ICH Tripartite regions, no testing at 25°C ± 2°C/60% RH ± 5% RH need be performed.

The use of long term testing at 30°C ± 2°C/65% RH ± 5% as a suitable alternative to 25°C ± 2°C/60% RH ± 5% for retest period or shelf life estimation in climatic zones I and II is acceptable for stable new drug substances and products.

But, it may result in a more restrictive retest period or shelf life estimation in climatic zones I and II for new drug substances and products with a limited stability at elevated temperature.

We recommend to clearly reinforce in the proposed Q1F guidance that the long-term storage condition at 30°C ± 2°C/65% RH ± 5% is only **OPTIONAL**.

The standard long-term storage condition for climatic zones I and II should remain at 25°C ± 2°C/60% RH ± 5%, which is considered as the mean kinetic temperature in these climatic zones.

In case of long term testing at 30°C ± 2°C/65% RH ± 5%, an acceptable approach for new drug substances and products with a limited stability at elevated temperature would be a reduced (e.g. annual) testing at 25°C ± 2°C/60% RH ± 5% for retest period or shelf life estimation in climatic zones I and II. This approach should remain an option, since it will not allow significant projection in term of shelf life considering the limited number of tested time points.

Page 2 – third paragraph
[Note: to harmonise the intermediate storage condition for Zones I and II with the long-term condition for Zones III and IV, the intermediate condition for the general case in the parent guideline will be changed to 30°C ± 2°C/65% RH ± 5% RH when this guideline reaches step 4]

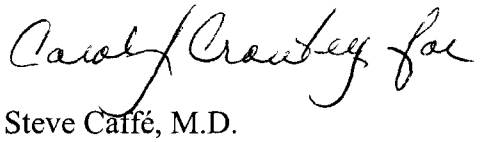
Since the intermediate storage condition for stability testing in climatic zones I and II will be modified in the parent guideline Q1A(R) from 30°C ± 2°C/60% RH ± 5% RH to 30°C ± 2°C/65% RH ± 5% RH, it is important to establish in the parent guideline a suitable transition period (e.g. 5 years) during which it will be acceptable to submit stability data on intermediate storage condition performed at 30°C ± 2°C/60% RH ± 5% RH.

2.3 Cautionary Note on Data Packages for Climatic Zones III and IV
It should be noted that not all drug substances and products intended for markets in Zones I and II in particular container closure systems will be suitable for Zones III and IV. In this case, a reduced retest period or shelf life should be considered. Alternatively, a more protective container closure system could be called for.
However, there may be examples in which a product cannot be demonstrated to be stable when stored at 30°C ± 2°C/65% RH ± 5% RH. In this case, additional cautionary statements in the labeling can be appropriate.

For new drug substances and products which are sensitive to temperature, stability data performed in accordance with ICH storage conditions required for climatic zones I and II that show stability failures at accelerated and intermediate storage conditions should be sufficient to support an additional cautionary statement for climatic zones III and IV. In this case, exposure to long term storage conditions required for climatic zones III and IV should not be deemed necessary in general.

On behalf of Aventis Pharmaceuticals Inc. we appreciate the opportunity to comment on Q1F Stability Data Package for Registration in Climatic Zones III and IV and thank you for your consideration.

Sincerely,



Steve Caffé, M.D.
Vice President, Head US Regulatory Affairs

0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research; FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In February 2002, the ICH Steering Committee agreed that a draft guidance entitled "S7B Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals" should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance provides general principles and information on currently available nonclinical methodologies to identify the potential risk of QT interval prolongation by a pharmaceutical and recommends study types and timing of studies in relation to clinical development of a pharmaceutical. The draft guidance is intended to protect clinical trial participants and patients receiving marketed products from delayed repolarization-associated ventricular tachycardia, torsade de pointes, and lethal arrhythmias resulting from administration of pharmaceuticals.

This draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by August 1, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/publications.htm.

Dated: June 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–15000 Filed 6–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0231]

International Conference on Harmonisation; Stability Data Package for Registration in Climatic Zones III and IV; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Q1F Stability Data Package for Registration in Climatic Zones III and IV." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This draft guidance, an annex to an ICH guidance entitled "Q1A(R) Stability Testing of New Drug Substances and Products," defines an approach for broader use of Q1A(R) for territories in climatic zones III and IV.

DATES: Submit written or electronic comments on the draft guidance by August 20, 2002.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Chi-wan Chen, Center for Drug Evaluation and Research (HFD–830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2001; or Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1148, 301–402–4635.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union (EU), Japan, and the United States. The six ICH sponsors are: The European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization (WHO), Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. Beginning April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In February 2002, the ICH Steering Committee agreed that a draft guidance entitled "Q1F Stability Data Package for Registration in Climatic Zones III and IV" should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

This draft guidance, an annex to an ICH guidance entitled "Q1A(R) Stability Testing of New Drug Substances and Products" (66 FR 56332, November 7, 2001), defines an approach for broader use of Q1A(R) for territories in climatic zones III and IV.

There are four climatic zones in the world that are distinguished by their characteristic prevalent annual climatic conditions, based on the concept described by P. Schumacher (*Pharmazeutische Zeitung*, 119:321–324, 1974). The Q1A(R) guidance defines the stability data package for the ICH tripartite regions (the EU, Japan, and the United States), which are in climatic zones I or II. The WHO has published a guideline entitled "Stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms" (WHO technical report series, no. 863, annex 5), updated in the "Report of the thirty-seventh meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations," Geneva, October 22–26, 2001. The WHO guideline defines stability testing recommendations, including storage conditions for all four climatic zones.

Harmonized global stability testing recommendations have been established in this draft guidance based on Q1A(R) and the WHO guideline. For territories in climatic zones III and IV, the data package as described in Q1A(R) can be considered applicable except for the defined long-term storage condition. The draft guidance recommends the long-term storage condition for a stability data package for registration of drug substances and products intended to be marketed in climatic zones III and IV.

When this draft guidance is finalized, Q1A(R) will be revised to harmonize the intermediate storage condition for zones I and II with the long-term storage condition for zones III and IV.

This draft guidance, when finalized, will represent the agency's current thinking on a stability data package for registration in climatic zones III and IV. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statues and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by August 20, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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Dated: June 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–14999 Filed 6–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

DRAFT CONSENSUS GUIDELINE

STABILITY DATA PACKAGE FOR REGISTRATION IN CLIMATIC ZONES III AND IV

Released for Consultation
at *Step 2* of the ICH Process
on 7 February 2002
by the ICH Steering Committee

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Steering Committee to the regulatory authorities of the three ICH regions (the European Union, Japan and the USA) for internal and external consultation, according to national or regional procedures.

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

STABILITY DATA PACKAGE FOR REGISTRATION IN CLIMATIC ZONES III AND IV

Draft ICH Consensus Guideline

Released for Consultation, **7 February 2002**, at *Step* 2 of the ICH Process

TABLE OF CONTENTS

STABILITY DATA PACKAGE FOR REGISTRATION IN CLIMATIC ZONES III AND IV

1. INTRODUCTION

1.1 Objectives of the Guideline

This guideline defines an approach for broader utility of the ICH Q1A(R) guideline on Stability Testing of New Drug Substances and Products (hereafter referred to as the parent guideline) for territories in Climatic Zones III and IV. (See Schumacher P., Aktuelle Fragen zur Haltbarkeit von Arzneimitteln [Current questions on drug stability] *Pharmazeutische Zeitung*, 1974, 119:321-324)

1.2 Background

The parent guideline defines the stability data package for the ICH tripartite regions (EC, Japan, and the United States). For other territories in Climatic Zones I or II, the parent guideline could be considered applicable, because the long term and accelerated storage condition defined within the guideline are based on an evaluation of climatic data from Zone II (which can be considered to cover Zone I, since Zone II is less temperate).

For territories in Climatic Zones III and IV, the data package as described in the parent guideline can be considered applicable except for the defined long term storage condition.

The World Health Organisation (WHO) has published a guideline on "Stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms" (WHO Technical Report Series, No 863, Annex 5), updated in the Report of the thirty-seventh meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, Geneva, 22-26 October 2001. It defines stability testing recommendations, including storage conditions for all four climatic zones. To facilitate the presentation of a global stability data package, thereby enabling timely access to new medicines in all territories of the world, harmonised global stability testing recommendations have been established based on the parent guideline and the WHO guideline.

1.3 Scope of the Guideline

This document is an annex to the parent guideline and recommends the long term storage condition to determine the data package considered sufficient for a registration application for drug substances and products intended to be marketed in Climatic Zones III and IV.

2. GUIDELINES

2.1 Continuity with the Parent Guideline

This guideline should be read in conjunction with the parent guideline and subsequently published annexes (Q1B, Q1D, Q1E). The recommendations in the parent guideline and annexes should be followed unless specific alternatives are described within this annex.

The following sections of the parent guideline can be considered common to any territory in the world and are not reproduced here:

- Stress testing
- Selection of batches
- Container closure systems
- Specifications
- Testing frequency
- Statements/labelling
- Refrigerated storage
- Freezer storage
- Semi-permeable or impermeable containers

2.2 Storage Conditions

For Climatic Zones III and IV, the recommended long term and accelerated storage conditions for the "General case" (as described in the parent guideline) are shown below:

Study	Storage condition	Minimum time period covered by data at submission
Long term	30°C ± 2°C/65% RH ± 5% RH	12 months
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months

For drug substances and products intended for registration applications within the ICH Tripartite regions, the parent guideline applies and long term testing will typically be conducted at 25°C ± 2°C/60% RH ± 5% RH. Where significant change occurs at any time during 6 months' storage at the accelerated condition, additional testing at the intermediate storage condition (30°C ± 2°C/65% RH ± 5% RH) should be conducted. Long term testing at 30°C ± 2°C/65% RH ± 5% RH can be a suitable alternative to 25°C ± 2°C/60% RH ± 5%. In this case, for an application in the ICH Tripartite regions, no testing at 25°C ± 2°C/60% RH ± 5% RH need be performed.

[Note: to harmonise the intermediate storage condition for Zones I and II with the long-term condition for Zones III and IV, the intermediate condition for the general case in the parent guideline will be changed to 30°C ± 2°C/65% RH ± 5% RH when this guideline reaches step 4]

Where appropriate, photostability testing should be conducted in accordance with the guidance given in ICH Q1B.

2.3 Cautionary Note on Data Packages for Climatic Zones III and IV

It should be noted that not all drug substances and products intended for markets in Zones I and II in particular container closure systems will be suitable for Zones III and IV. In this case, a reduced retest period or shelf life should be considered. Alternatively, a more protective container closure system could be called for.

However, there may be examples in which a product cannot be demonstrated to be stable when stored at 30°C ± 2°C/65% RH ± 5% RH. In this case, additional cautionary statements in the labeling can be appropriate.

If special transportation and storage conditions are identified as being outside the proposed storage criteria, additional study data should be made available, for example up to 3 months at 45–50°C and for Zone IV, 75% relative humidity (RH).

ERIC ALBEE
(908) 304-6201
AVENTIS PHARMACEUTICALS
200 CROSSINGS BLVD
BRIDGEWATER NJ 08807

LTR 1 OF 1

SHIP TO:
DOCKETS MANAGEMENT BRANCH
(301) 827-6860
FOOD & DRUG ADMINISTRATION
HFA-305
ROOM 1061
5630 FISHERS LANE
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REF 2: DF

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